Obviousness Rejection

Claims 1-13 were rejected under 35 USC §103(a) as being unpatentable over U.S. Pat. No. 4,327,076 ("Puglia") in view of U.S. Pat. No. 5,380,541 (Office Action at 2.)

For the reasons set forth below the rejection, respectfully is traversed.

Puglia discloses

[57] **ABSTRACT**

An improved compressed soft chewable tablet is provided, which may contain an antacid or other active ingredient, has good flexibility, is breakage resistant and disintegrates immediately upon chewing. The tablet of the invention is formed of particles of antacid and/or other active ingredient which are isolated from other ingredients of the tablet, preferably by admixing particles of active ingredient with particles formed of edible fat or oil absorbed on a fat-absorbing material, such as microcrystalline cellulose and blending such particles with one or more tablet bonders; the tablet also includes additional amounts of tablet bonders, flavors and other conventional tabletting aids to help in making the tablet more palatable. Upon chewing, the tablet is quickly converted to a smooth creamy non-gritty palatable emulsion.

Abstract

resistant and yet may be easily chewed and quickly disintegrated and dissolved in the mouth. The compressed chewable tablet of the invention includes (a) a particulate pretreated fat composition formed of an edible fatty material, a fat-sorbing material having the fatty material sorbed thereon or therein, and one or more tablet bonders blended therewith, and optionally one or more antioxidants, flavors and/or colorant; (b) a pretreated active ingredient composition formed of a mixture of particles of active ingredient, such as particles of one or a mixture of antacids, and optionally edible oil, binder, emulsifier, flavor, and colorant, the particles of active ingredients being coated with the other components of said pretreated active ingredient composition; and (c) a pretreated direct compaction tabletting aids composition including bonders and optionally flavors, the compositions (a), (b) and (c) being blended together and the blend being in the form of said compressed chewable tablet.

Col. 2

In a preferred embodiment of the compressed chewable tablet of the invention, the active ingredient is comprised of particles of one or more antacids so that the particulate pretreated fat composition (a) will include a fat-sorbing material, preferably microcrystalline cellulose, a fatty material absorbed in the microcrystalline cellulose, optionally a colorant, such as titanium dioxide, optionally an antioxidant, such as butylated hydroxytoluene, optionally an antiflatulent, such as simethicone, tablet bonders, preferably tabletting sugar and/or dextrose monohydrate, and optionally one or more flavors.

The preferred pretreated active ingredient composition (b) will include particles of one or more antacids, such as calcium carbonate, aluminum hydroxide and/or magnesium hydroxide, and preferably a mixture of all of said antacids, a binder, preferably carboxymethyl cellulose, to help flavor and emulsifier to stick to fat absorbed particles and impart a slippery mouth feel, an emulsifier, such as polyglycerol ester of fatty acids, to help decrease surface tension on the tongue and stimulate salivation, an edible oil, preferably a vegetable oil, to help plating out of the emulsifier on the antacid particles, and flavor.

The preferred pretreated direct compaction tabletting aids composition (c) will include tablet bonders, preferably tabletting sugar and/or dextrose monohydrate, and flavors and flavor oils. Col. 3.

The compressed chewable tablet of the invention includes particles of active ingredient, such as antacids, vitamins, laxatives, antiflatulents, aspirin, acetaminophen, appetite depressants and the like and will have a non-chalky non-gritty pleasant taste and when exposed to saliva in the mouth converts to an emulsion or colloidal suspension and thus behaves as would a liquid. Also, since the tablet of the invention will disintegrate rapidly Col. 4

The active ingredient, depending upon the specific properties thereof, will generally comprise from about 90 to about 99.9% and preferably from about 92 to about 97% by weight of the pretreated active ingredient composition, and from about 10 to about 50% and preferably from about 15 to about 30% by weight of the final tablet. Col. 4

The fats or oils used may be of animal, vegetable or mineral origin which are substantially water-insoluble, inert, non-toxic hydrocarbon fats and oils and derivatives thereof and may comprise any of the commonly commercially available fats or oils approved by the Food and Drug Administration and having melting points constant with desired mouth feeling factors, such as melting points ranging from 80° to 110° F. and need not be limited to melting points above body temperature. The fats or oils will be employed in amounts within the range of from about 2 to about 45%, and preferably from about 10 to about 25%, depending upon the properties desired in the final product. Examples of Col. 4

The fat-sorbing materials (that is, fat-absorbing and/or fat-adsorbing material) which may be present herein include microcrystalline cellulose, cornstarch, tapioca, dextrin, sucrose, sorbitol, xylitol, mannitol and the like with microcrystalline cellulose being preferred. The fat-sorbing material will be present in the pretreated fat composition in an amount of from about 25 to about 75% and preferably from about 40 to about 60% by weight of said pretreated fat composition and will be employed in a weight ratio of the fatty material of from about 0.625:1 to about 1.815:1 and preferably from about 1:1 to about 1.5:1; the fat-sorbing material will be present in the finished tablet formulation in an amount of from about 10 to about 30% and preferably from about 10 to about 20% by weight. Col. 5

The edible oil in the pretreated active ingredient composition, which aids in plating out emulsifier on particles of active ingredient, will be present in an amount within the range of from about 1 to about 4%, and preferably from about 1.5 to about 2.5% and may include any of the edible oils disclosed with respect to the fatty materials set out above.

Any emulsifier or surfactant approved for use in foods by the Food and Drug Administration and having an HLB value of 8 and above, may be employed in the pretreated active ingredient composition in forming antacid tablets of the invention in amounts ranging from about 0.05 to about 2.5% by weight and preferably in amounts ranging from about 0.1 to about 1.0% by weight based on the final tablet formulation, and from about 1 to about 4% and preferably from about 1.5 to about 2.5% based on the weight of the pretreated active ingredient composition. Col. 5

The slip agent present in the pretreated active ingredient composition includes cellulose gums, such as carboxymethyl cellulose gum, xanthan gum, locust bean gum, alginic acid, or mixtures thereof and will be present in an amount of within the range of from about 1 to about 5% by weight of the pretreated active ingredient composition, and from about 2.5 to about 3.5%, and preferably from about 0.75 to about 1.5% based on the weight of the finished tablet. Col. 6.

The following are preferred chewable tablet formulations in accordance with the present invention:

		% by Wt. based on pretreated composition	% by Wt. based on total tablet
I.	Pretreated Fat Composition		
(a)	Fatty material (preferably hydrogenated vegetable oil)	30 to 50	10 to 20
(b)	Fat-sorbing material (preferably microcrystalline cellulose)	25 to 35	10 to 15
(c)	Tabletting bonders (preferably tabletting sugar and dextrose monohydrate)	20 to 30	7.5 to 15
(d)	Flavor	0.1 to 0.4	0.05 to 0.15
(e)	Colorant	0.05 to 0.4	0.1 to 0.3
(f)	Antioxidant	0.05 to 0.1	0.01 to 0.03
	Pretreated		
II.	Active Ingredient Composition		
(g)	Active ingredient (Preferably antacid		
	$CaCO_3$	50 to 60	10 to 15
	$Al(OH)_3$	15 to 25	3 to 6
	$Mg(OH)_2$)	15 to 25	3 to 6
(h)	Slip agent (preferably carboxymethyl cellulose)	1.5 to 4	0.5 to 1.5
(i)	Emulsifier (preferably polyglycerol ester of fatty acid)	1 to 3	0.25 to 0.75
(j)	Edible oil (preferably hydrogenated vegetable oil)	1 to 3	0.25 to 0.75
(k)	Flavor	0.2 to 0.5	0.05 to 0.15
	Pretreated		
III.	Tabletting Aids Composition		
(l)	Tablet bonders (preferably tabletting sugar and dextrose monohydrate)	95 to 99.9	30 to 40
(m)	Flavor	1.5 to 5	0.1 to 1

Col. 7.

EXAMPLE 1

A chewable antacid tablet is prepared as described below from the following three premixes.

Premix I (Pretreatment of Fat System)	Parts by Weight of Total Tablet
1. Hydrogenated vegetable oil (Satina II NT)	16.225
2. Microcrystalline cellulose (Avicel pH 102 - particle size 90μ)	12.27
3. Titanium dioxide (colorant)	0.03
4. Simethicone LVA (antiflatulent)	1
5. Dextrose monohydrate (Cantab)	10
6. Artificial vanilla flavor	0.1
7. Butylated hydroxytoluene (antioxidant)	0.01

Premix II (Pretreatment of Antacid Material for Improved Palatibility)	Parts by Weight of Total Tablet
8. $CaCO_3$	13
9. $Al(OH)_3$	5
10. $Mg(OH)_2$	4
11. Carboxymethyl cellulose	0.75
12. Emulsifier (polyglycerol esters of fatty acids) (Santone 8-1-0)	0.5
13. Vegetable oil (Durkex 500)	0.5
14. Artificial vanilla flavor	0.1

Premix III (Pretreatment of Direct Compaction Tabletting Aids)	Parts by Weight of Total Tablet
15. Dextrose monohydrate	23
16. Tabletting sugar	12.5
17. Artificial vanilla flavor	0.4
18. Peppermint oil	0.1

Beyts discloses

[57] **ABSTRACT**

Synergy is is obtained by combining sucralose and a sweet saccharide selected from fructose; glucose; maltose and other glucooligosaccharides; fructose mixed with glucose and/or gluco-oligosaccharides; lactose; isomaltulose; and sugar alcohols.

According to the present invention there is provided a sweetening composition for sweetening ingestible compositions and oral products, the composition consisting essentially of sucralose; a sweet saccharide selected from fructose; glucose; maltose and other glucooligosaccharides; glucose mixed with maltose and other oligosaccharides; fructose mixed with glucose and/or gluco-oligosaccharides, lactose, isomaltulose, and sugar alcohols, and, optionally, a carrier for a sweetening composition; the relative sweetness contribution provided by the sucralose and the sweet saccharide being from 5:1 to 1:5. By the term "sweetening composition", we mean a composition for use in sweetening foodstuffs, beverages etc, e.g. sweetening tablets and granules, concentrates for the beverage industry etc. (Col. 2.)

EXAMPLE 9

Peppermint tablet

	Sorbitol % w/w	Mannitol % w/w	Xylitol % w/w
Sucralose	0.01	0.01	0.005
Sorbitol[1]	98.19	—	—
Mannitol[1]	—	98.19	—
Xylitol[1]	—	—	98.195
Magnesium Stearate[2]	1.00	1.00	1.00
Peppermint Durarome[3] sugar free 186292	0.80	0.80	0.80

1. Roquette (UK) Ltd.
2. Croxton & Garry Ltd, U.K.
3. Semmens Taylor Ingredients, U.K.

In making the rejection, the Examiner asserted

> Puglia teaches compressed soft chewable antacid tablets that are break resistant and yet fast disintegrating upon chewing. The tablet of Puglia containing antacid particles is mixed with oil or fat absorbed on a fat-absorbing material such as microcrystalline cellulose and tablet binders such as dextrose hydrate, sugars etc (col. 2, lines 46-67, Example 1 & col. 5, lines 22-32). Puglia further teaches addition of sweetening agents such as sugar, saccharin, aspartame etc in the antacid composition (col. 6, lines 40-54). In addition to antacid, Puglia teaches chewable tablets comprising other medicaments such as aspirin, vitamins etc (col. 9). Puglia teaches addition of fats or oil in an amount of 2% to 45%, which includes the claimed percentage of fat (col. 4, lines 53-65). Puglia does not specifically teach particulate dextrose monohydrate.

(Office Action at 2.)

> However, the reference teaches blending the dextrose monohydrate with other components of the tablet (col. 8) and thus obviously resulting in a particulate material before being compressed. Puglia fails to teach sucralose of the instant claims.

(Office Action at 3.)

To fill the acknowledged gap, the Examiner relied upon Beyts as follows:

> Beyts teaches sucralose containing ingestible compositions such as medicaments, beverages, etc. Beyts teaches that a synergy in obtaining sweetness is observed with sucralose and other saccharides such as glucose, fructose, mannitol, sorbitol, or fructose mixed with glucose. Example 1 of Beyts shows the synergy of sucralose with various sweeteners such as fructose etc., and the list of sweetener blends with sucralose in col. 5, specifically mentions a combination of dextrose monohydrate and sucralose that reads on the instant claimed components. Further example 9 is directed to a peppermint tablet, which meets the description of a chewable tablet. Accordingly, it would have been obvious for one of an ordinary skill in the art at

(*Id.*)

The Examiner concluded as follows:

> tablet. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add a synergistic combination of sucralose with other sweeteners such as fructose, dextrose monohydrate, sucrose, glucose etc., of Puglia because Beyts suggests that sucralose is effective in reducing the calorie level in the final preparation of foodstuff, medicaments, beverages etc. and is much sweeter than the sucrose or other sweeteners. Accordingly, one of an ordinary skill in the art would have expected to sweeten the chewable tablet composition of Puglia by adding sucralose together with other sweeteners such that the sweetness intensity of the composition is increased due to the presence of sucralose and yet with low calories.

(*Id.*)

Initially, it is noted that claims 1-13 affirmatively require that the matrix is substantially free of non-saccharide, water soluble polymeric binders The rejection fails to identify where in Puglia such a limitation can be found.

As is fundamental, a *prima facie* case of obviousness must be based on facts, "cold hard facts." When the rejection is not supported by facts, it cannot stand.

Nor is it believed that the Examiner can find the requisite teaching, suggestion, or motivation for the required claim limitation. The Examiner's attention is directed to page 5, lines 29-31, wherein it is disclosed that "water-soluble, non-saccharide polymeric binders such as polyvinyl pyrrolidone, algninates, hydroxypropyl cellulose, hydroxypropylmethylcellulose, hydroxyethylcellulose, and the like."

Puglia requires a slip agent from about 0.75 to about 1.5% based on the weight of the finished tablet or 0.5 to 1.5% by weight based on the total tablet. (Col. 6, lns. 10-18, and col. 7 lns. 27-29.) The slip agent includes, among others, carboxymethyl cellulose gum. It is submitted that carboxymethylcellulose gum is a non-saccharide, water soluble polymeric binder. A chewable antiacid tablet of Example 1 affirmative uses 0.75 parts by weight of the total tablet of carboxymethylcellulose. Further, claim 4 of Puglia discloses that carboxymethyl cellulose is a binder. It is believed that the above does not teach, suggest, or provide the requisite motivation for one of ordinary skill in the art to do as the

present inventor has done, including a tablet that is less than 5% by weight of fat and a matix that is substantially free of a non-saccharide, water soluble polymeric binder. For this reason, the rejection is not supported and should be withdrawn.

When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references Stated another way, the prior art as a whole must "suggest the desirability"of the combination. The source of the teaching, suggestion, or motivation may be "the nature of the problem," "the teachings of the pertinent references,"or "the ordinary knowledge of those skilled in the art."

It is not seen where Beyts discloses or suggests the desirability of including sucralose in a chewable medicament or tablet. At best, Example 9 is a peppermint tablet, which appears to be a succulent tablet. As is well settled, an Examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would ***impel*** one skilled in the art to do what the patent applicant has done. Thus, the rejection fails to set forth the required facts and reasoning required to support a *prima facie* case of obviousness. For this additional reason the rejection should be withdrawn.

Finally, the Examiner is invited to call the applicants' undersigned representative if any further action will expedite the prosecution of the application or if the Examiner has any suggestions or questions concerning the application or the present Response. In fact, if the claims of the application are not believed to be in full condition for allowance, for any reason, the applicants respectfully request the constructive assistance and suggestions of the Examiner in drafting one or more acceptable claims pursuant to MPEP § 707.07(j) or in making constructive suggestions pursuant to MPEP § 706.03 so that the application can be placed in allowable condition as soon as possible and without the need for further proceedings.

Respectfully submitted,
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